Billing Code 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances

Notice of Application

Almac Clinical Services, Inc., (ACSI)

Pursuant to 21 CFR 1301.34 (a), this is notice that on March 5, 2014, Almac Clinical Services, Inc., (ACSI), 25 Fretz Road, Souderton, Pennsylvania 18964, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the following basic classes of controlled substances:

Drug	Schedule
Oxycodone (9143)	II
Hydromorphone (9150)	II
Tapentadol (9780)	II
Fentanyl (9801)	II

The company plans to import small quantities of the listed controlled substances in dosage form to conduct clinical trials.

The import of the above listed basic classes of controlled substances will be granted only for analytical testing and clinical trials. This authorization does not extend to the import of finished FDA approved or non-approved dosage forms for commercial distribution in the United States.

Any bulk manufacturer who is presently, or is applying to be, registered with the DEA to manufacture such basic classes of controlled substances listed in schedule II, which falls under the authority of section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)) may, in the circumstances set forth in 21 U.S.C. 958(i), file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODW), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than [INSERT DATE 30 DAYS FROM DATE OF PUBLICATION].

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR

1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the Federal Register on September 23, 1975, 40 FR 43745-46, all applicants for registration to import a basic class of any controlled substances in schedules I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration

DATED: April 21, 2014

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